



OLIVER B. MITCHELL III
PO BOX 1705
LONG BEACH, CALIFORNIA 90801
PH: (562) 719-3872
FAX: (888) 829-7124
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IN PRO PER

LACV1903610 - PA-JPRx
UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT COURT OF CALIFORNIA

OLIVER B. MITCHELL III,
Plaintiff,

vs.

OCTAPHARMA AG; and STAFFORD,
OWENS, PILLER, MURANE,
KELLEHER & TROMBLEY, PLLC.,
Defendant.

CASE NUMBER _____

COMPLAINT FOR INJUNCTIVE RELIEF

COMPLAINT FOR INJUNCTIVE RELIEF

INTRODUCTION

1. This is an action under the Freedom of Information Act ("FOIA") seeking the release of clinical records relating to the Plaintiff participation in plasma donations and Octapharma AG policy to withhold documents otherwise subject to a Freedom of Information Act request for reasons outside the statutory exemptions.

2. Plaintiff, Oliver B. Mitchell III, sought access to records related to his plasma donations at Octapharma Plasma located at 6454 Van Nuys Blvd., Ste 100, Van Nuys, CA 91401. This case concerns documents that Mr. Mitchell identified as responsive but Octapharma AG failed to disclose. Instead, Octapharma AG and Stafford, Owens, Piller, Murnane, Kelleher & Trombley, PLLC denied the request saying "Please be advised that Octapharma does not operate medical facilities, and therefore, does not maintain any medical records. Furthermore, my client does not issue bills or invoices to its donors, nor does it maintain research files with respect to its donors. Therefore,

1 the documentation that you have requested be provided does not exist, and therefore, cannot be
2 provided to you,” thus, prompting this litigation. Because this justification for denial does not fall
3 within one of the statutorily designated exemptions to the FOIA, Defendants improperly withheld
4 clinical records from Mr. Mitchell.

5 3. Clinical Trials are “experiments” or observations done in clinical research. Such
6 prospective “biomedical” or “behavioral” research studies on human participants are designed to
7 answer specific questions about biomedical or behavioral interventions. Octapharma AG, founded in
8 1983, is a family-owned pharmaceutical company, and bills itself as “one of the largest human
9 protein manufacturers in the world, developing and producing human proteins from human plasma
10 and human cell lines.

11 4. On February 26, 2019, Mr. Mitchell first began to request documents under the FOIA
12 from Defendants Octapharma Plasma and Stafford, Owens, Piller, Murnane, Kelleher & Trombley,
13 PLLC. To date, the Plaintiff has not received the documents as indicated in his request.

14 5. The Plaintiff is legally entitled to these documents, which were requested over thirty
15 days ago. Octapharma AG has far exceeded the statutory and regulatory time limitation to respond to
16 the Plaintiffs request.

17 6. Given the seriousness of the violations at hand, it is of concern that the requested
18 documents are disclosed to the Plaintiff. Accordingly, this Court should order Defendants to provide
19 the requested records to Mr. Mitchell immediately.

20 **JURISDICTION & VENUE**

21 7. This Court has subject matter jurisdiction over this action and personal jurisdiction
22 over the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 5 U.S.C. § 552(a)(4)(A)(vii). This Court also
23 has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701–706.

24 8. Because Defendant failed to comply with the requirements to respond set forth in 5
25 U.S.C. § 552(a)(6)(A), Plaintiffs have constructively exhausted their administrative remedies and are
26 entitled to proceed with this judicial action pursuant to 5 U.S.C. § 552(a)(6)(C)(i).
27
28

1 Octapharma compiles, records and stores donor medical information... Medical records are legal
 2 documents that can be used as evidence via a subpoena duces tecum, and are thus subject to the laws
 3 of the country/state in which they are produced. As such, there is great variability in rules governing
 4 production, ownership, accessibility, and destruction. In the United States, the data contained within
 5 the medical record belongs to the patient, whereas the physical form the data takes belongs to the
 6 entity responsible for maintaining the record per the Health Insurance Portability and Accountability
 7 Act. Therefore, in accordance with the 21st Century Cures Act, the California Public Records Act
 8 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts
 9 160 and 164, I am requesting copies of "any and all records pertaining to my donations" at
 10 Octapharma Plasma located at 6454 Van Nuys Blvd., Ste 100, Van Nuys, CA 91401. **EXHIBIT 3**

11 **CAUSES OF ACTION**

12 16. The Plaintiff repeats and realleges paragraphs 1 -15.

13 17. Defendants failure to timely respond to the Plaintiffs request violates the FOIA, 5
 14 U.S.C. § 552(a)(6)(A)(ii), and the California Public Records Act 6250 et seq.
 15

16 18. Defendants' failure to make a reasonable effort to search for records responsive to the
 17 Plaintiffs request violates the FOIA, 5 U.S.C. § 552(a)(3)(C), and the California Public Records Act
 18 6250 et seq.

19 19. Defendants' wrongful withholding of non-exempt responsive materials violates the
 20 FOIA, 5 U.S.C. § 552(a)(3)(A).

21 **PRAYER FOR RELIEF**

22 WHEREFORE, Plaintiff respectfully request that this Court enter a judgment for Plaintiff and
 23 award the following relief:

24 a. Order Defendant, by a date certain, to conduct a search that is reasonably likely to lead
 25 to the discovery of any and all records responsive to Plaintiffs' February 26 and March 25 Requests;

26 b. Order Defendant, by a date certain, to demonstrate that it has conducted an adequate
 27 search;
 28

1 c. Order Defendant, by a date certain, to produce to Plaintiffs any and all nonexempt
2 records or portions of records responsive to Plaintiffs' February 26 and March 25 Requests, as well as
3 a Vaughn index of any records or portions of records withheld due to a claim of exemption;

4 d. Enjoin Defendant from withholding the requested records;

5 e. Enjoin Defendants from charging Plaintiff fees for the processing of their request;

6 f. Award Plaintiff its costs and attorney's fees reasonably incurred in this action,
7 pursuant to 5 U.S.C. § 552(a)(4)(E); and

8 g. Grant Plaintiffs such other and further relief as the Court may deem just and proper.
9

10 Respectfully submitted this 29th day of April 2019.
11
12
13

14 

15 Oliver B. Mitchell III (Pro Se)

16 PO Box 1705

17 Long Beach, CA

18 90801

19 Tel: (562) 719-3872

20 Fax: (888) 829-7124

21 redpatchmarine@hotmail.com
22
23
24
25
26
27
28

OLIVER B. MITCHELL III

VS

**OCTAPHARMA PLASMA; and
STAFFORD, OWENS, PILLER, MURANE,
KELLEHER & TROMBLEY, PLLC.**

EXHIBITS

1 - 3

Fax Message Transmission Result to +1 (704) 6544700 - Sent

RingCentral <service@ringcentral.com>

Wed 2/27/2019 2:20 PM

To: Oliver Mitchell <redpatchmarine@hotmail.com>

Here are the results of the 3-page fax you sent from your phone number (888) 829-7124:

Name	Phone Number	Date and Time	Result
	+1 (704) 6544700	Wednesday, February 27, 2019 at 02:19 PM	Sent

Your fax(es) included the following file(s), which were rendered into fax format for transmission:

File Name	Result
OCTAPHARMA PLASMA FOIA REQUEST.docx	Success

**Oliver Bruce Mitchell III
PO Box 1705
Long Beach, California
90801**

February 26, 2019

SENT VIA FAX AND USPS MAIL

**Octapharma Plasma, Inc
16044 Westlake Drive
Charlotte, NC
28273
Ph (704) 654-4600
Fax (704) 654-4700**

**Octapharma Plasma
6454 Van Nuys Blvd
Suite 100
Van Nuys, CA
91401
Office: (818) 997-6033**

Subj: HIPAA Privacy Authorization Form

Dear Octapharma Plasma,

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

Octapharma Plasma specializes in “the safe and optimal use of human proteins.”

Clinical research ethics are the set of relevant ethics considered in the conduct of a clinical trial in the field of clinical research. It borrows from the broader fields of research ethics and medical ethics.

Return of results is a concept in research ethics which describes the extent of the duty of a researcher to reveal and explain the results of research to a research participant. Return of results is particularly discussed in the field of biobanks, where a typical case would be that many members of a community donate biobank specimens for medical research. In the course of the research, especially in human genomics research, scientists may discover personal health information which could influence the behavior of specimen donors if they had this information.

In accordance with the 21st Century Cures Act, the California Public Records Act 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts 160 and 164, I am requesting copies of all records pertaining to my donations at Octapharma Plasma located at 6454 Van Nuys Blvd., Ste 100, Van Nuys, CA 91401.

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in my best interest and will contribute significantly to my understanding of your clinical research. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health and billing records.
2. Copies of all records and notes within the patients' medical/research file.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided:

Please mail all records to the above address.

Thank you for considering my request.

Sincerely,

☐

X 

Oliver B. Mitchell III

Signed by: Oliver B. Mitchell III



STAFFORD • OWENS

PILLER • MURNANE • KELLEHER & TROMBLEY, PLLC

Attorneys & Counselors at Law

One Cumberland Avenue

PO Box 2947

Plattsburgh, NY 12901

P 518.561.4400

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staffordowens.com

William L. Owens
Edward J. Trombley
Susanna S. Piller
Thomas M. Murnane
Jacqueline M. Kelleher
Jessica L. Miller
Justin R. Meyer
Brendan P. Owens
Meghan E. Zedick

Maxwell C. Radley

March 19, 2019

Oliver B. Mitchell, III
PO Box 1705
Long Beach, CA 90801

Re: Request for Medical/Research Records

Dear Mr. Mitchell:

Our firm represents Octapharma Plasma, Inc. ("Octapharma"). Please direct all future communication regarding this matter to me. I am writing in response to your letter to Octapharma dated February 26, 2019 requesting that Octapharma provide: (1) copies of all health and billing records; and (2) copies of all records and notes within the patients' medical/research file. Please be advised that Octapharma does not operate medical facilities, and therefore, does not maintain any medical records. Furthermore, my client does not issue bills or invoices to its donors, nor does it maintain research files with respect to its donors. Therefore, the documentation that you have requested be provided does not exist, and therefore, cannot be provided to you.

If you have what you believe to be pertinent medical records, invoices or any other information related to an incident that involves Octapharma, please provide me with copies of such documents for Octapharma's review. Please be advised that by agreeing to consider an amicable resolution, Octapharma does not acknowledge responsibility or liability. Octapharma expressly reserves all rights to fully defend itself in this matter in any future litigation.

Please feel free to contact me should you have any questions.

Very truly yours,

STAFFORD, OWENS, PILLER, MURNANE,
KELLEHER & TROMBLEY, PLLC

By: Jessica L. Miller, Esq.

Ronald B. Stafford
(1935-2005)

cc: Octapharma Plasma, Inc.

Fax Message Transmission Result to +1 (518) 5614848 - Sent

RingCentral <service@ringcentral.com>

Mon 3/25/2019 8:43 AM

To: Oliver Mitchell <redpatchmarine@hotmail.com>

Here are the results of the 7-page fax you sent from your phone number (888) 829-7124:

Name	Phone Number	Date and Time	Result
	+1 (518) 5614848	Monday, March 25, 2019 at 08:42 AM	Sent

Your fax(es) included the following file(s), which were rendered into fax format for transmission:

File Name	Result
OCTAPHARMA PLASMA STAFFORD OWENS.docx	Success

Oliver Bruce Mitchell III
PO Box 1705
Long Beach, California
90801
PH: (562) 719-3872
FX: (888) 829-7124

March 25, 2019

SENT VIA FAX

Stafford, Owens, Piller, Murnane, Kelleher & Trombley, PLLC
P.O. Box 2947
One Cumberland Avenue
Plattsburgh, NY 12901
Ph 518.561.4400
Fx 518.561.4848

Re: Request for Medical/Research Records

Dear Ms. Jessica L. Miller Esq.,

Thank you for your response. I have received your response dated March 19, 2019, Postmarked March 19, 2019, and received on March 23, 2019. I offer the following.

Octapharma AG, founded in 1983, is a family-owned pharmaceutical company, and bills itself as "one of the largest human protein manufacturers in the world, developing and producing human proteins from human plasma and human cell lines.

Octapharma medicines treat a broad range of rare and life-threatening congenital and acquired diseases to include, bleeding disorders (haemophilia A / B and VWD), over 300 types of primary and secondary immune deficiencies, numerous auto-immune and neurological disorders, acute conditions/in critical care (including trauma and burn victims), cancer patients and during major surgeries new-borns are also protected in case of Rh negative pregnancies.

Octapharma converts source plasma into plasma protein products through fractionation and processing. Each therapy created is controlled, fractionated, purified, virus inactivated and inspected before being used.

Octapharma owns six production facilities in Austria, France, Germany, Sweden and Mexico, and also 13 plasma donation centers in Europe and 86 the United States. Octapharma collects plasma and manufactures it into lifesaving plasma-derived therapies.

Octapharma Plasma specializes in “the safe and optimal use of human proteins.”

In your letter to me, 1st Page, 1st Paragraph, Lines 5-9, you state “Please be advised that Octapharma does not operate medical facilities, and therefore, does not maintain any medical records. Furthermore, my client does not issue bills or invoices to its donors, nor does it maintain research files with respect to its donors. Therefore, the documentation that you have requested be provided does not exist, and therefore, cannot be provided to you.”

As previously indicated above, Octapharma Plasma operates 86 plasma donation centers in the United States.

Per Octapharma Plasma:

1. Donation requirements

When you come to a plasma center for the first time, please bring a current, valid photo ID (like your driver’s license), proof of your Social Security number, and proof of your current address (for example, a letter or bill that came to you in the mail in the past 30 days or a current lease).

During your visit, we’ll do a health screening, review an in-depth medical questionnaire, and take blood samples* to make sure you can donate. In addition, you must:

- Be in good health, meaning you feel well and can do normal everyday activities.

- Be between the ages of 18 and 66.

- Have a healthy vein in your arm for drawing blood.

- Weigh at least 110 pounds.

Not have gotten ear piercings, body piercings, tattoos or permanent makeup in the past 12 months.

If you have Rh-negative blood, we especially need your donations for our specialty antibody program. The staff at your nearest Octapharma Plasma donation center can tell you more about this program.

* Blood testing screens for hepatitis, the human immunodeficiency virus (HIV) and syphilis.

2. Medical conditions

Specific medical conditions may or may not affect your ability to donate plasma. For example, high or low blood pressure is okay within certain limits; so is diabetes if it's well controlled. Check with your local Octapharma Plasma donation center for more information about how your medical condition might affect your ability to donate plasma.

3. What should I expect during my first plasma donation?

Your first visit can take up to 2 hours because it includes a health screening and tests to make sure you can donate plasma. After that, each visit takes less time – about an hour to an hour and a half.

Here's more on what to expect during your first visit:

1. Check in

A staff member will greet you and ask for a current, valid photo ID, proof of your Social Security number, and proof of your current address (for example, a letter or bill that came to you in the mail in the past 30 days or a current lease).

2. Watch a short video

You'll spend a few minutes watching an educational video about the plasma donation process.

3. Complete your screening

We'll take your medical history, review an in-depth health questionnaire, talk about what confidential informed consent means, explain the plasma donation process, run blood tests, and answer your questions.

4. Donate
5. You'll go to a special area and begin the donation process. A trained staff member called a phlebotomist will put a sterile needle in a vein in your arm to draw your blood. Most people compare the feeling to a prick or a pinch like you would feel when donating blood.
6. Next, you'll relax while your blood cycles through special, sterile equipment that separates plasma from the other parts of your blood. To pass the time, you can use our free Wi-Fi on your smartphone or tablet or watch our TVs. You can also bring books, magazines, and music (with headphones, of course).
7. A staff member will check on you during the process to make sure you're comfortable and answer your questions.
8. Get paid

After your first plasma donation is complete, you'll receive your payment on an Octapharma Plasma Prepaid debit card. The card is reloaded after every successful plasma donation you make.

9. Come back for your second visit

Your second plasma donation is very important!

The first time you donate plasma, we test your donation sample to make sure it's safe to use in life-saving medicines. We can't use your first plasma donation until after you make your second one, so don't forget to come back to donate again 2 to 14 days after your first visit.

You can donate as frequently as 2 times in 7 days, with at least 2 days between donations. So if you donate on a Monday, you can donate again Wednesday.

For tips on what to do to get your body ready to donate plasma again, visit our Health & Nutrition page.

Source:

Current as of 03/25/19

Again, your claim that Octapharma “does not operate medical facilities, and therefore, does not maintain any medical records” is “half true.” Octapharma may not operate medical facilities, however, through its “donor centers” Octapharma “compiles, records, and stores” donors medical information.

The terms medical record, health record, and medical chart are used somewhat interchangeably to describe the systematic documentation of a single patient's medical history and care across time within one particular health care provider's jurisdiction.

The medical record includes a variety of types of “notes” entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, x-rays, reports, etc. The maintenance of complete and accurate medical records is a requirement of health care providers and is generally enforced as a licensing or certification prerequisite.

Medical records are legal documents that can be used as evidence via a subpoena duces tecum, and are thus subject to the laws of the country/state in which they are produced. As such, there is great variability in rules governing production, ownership, accessibility, and destruction.

In the United States, the data contained within the medical record belongs to the patient, whereas the physical form the data takes belongs to the entity responsible for maintaining the record per the Health Insurance Portability and Accountability Act.

Again, you claim, Octapharma does not “maintain any medical records” and by all accounts this communication has established that Octapharma does in fact “maintain, document, record, and compile” donors medical information.

Therefore, in accordance with the 21st Century Cures Act, the California Public Records Act 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts 160 and 164, I am requesting copies of “any and all records pertaining to my donations” at Octapharma Plasma located at 6454 Van Nuys Blvd., Ste 100, Van Nuys, CA 91401.

Again, allow me to CLARIFY; that’s “any and all records pertaining to my donations.”

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in

that the disclosure of the requested information is in my best interest and will contribute significantly to my understanding of your clinical research. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health records and notes within my donor/medical file.

Secondly, in your letter to me, 1st Page, 2nd Paragraph, Lines 1-3, you state "If you have what you believe to be pertinent medical records, invoices or any other information related to an incident that involves Octapharma, please provide me with copies of such documents for Octapharma's review."

Please be advised at this time, that there are no documents or any other information that is and/or was prepared for Octapharma's review. In fact, this is simply a request for health information contained within the "donors" files maintained at the donor center.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided:

Mitchell, 3512

Please mail, fax and/or email all records to the above address.

Thank you for considering my request.

Sincerely,





Oliver B. Mitchell III

Signed by: Oliver B. Mitchell III